IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS

CHILDREN'S HEALTH DEFENSE, DEBORAH L. ELSE, an individual, and SACHA DIETRICH, an individual,	)	**Case No. 6:22-cv-93**
	)	**Date: _____**
Plaintiffs,	)	**Time: _____**
v.	)	**Dept: _____**
FOOD and DRUG ADMINISTRATION, and JANET WOODCOCK, Acting Commissioner of Food and Drug Administration,	)	
Defendants.	)	

PLAINTIFFS' MOTION TO STAY THE FOOD and DRUG ADMINISTRATION'S EMERGENCY USE AUTHORIZATION OF THE PFIZER-BIONTECH COVID-19 VACCINE FOR CHILDREN AGES FIVE THROUGH ELEVEN

TO THE HONORABLE JUDGE OF THE COURT:

COME NOW Plaintiffs Children's Health Defense ("CHD"), Deborah L. Else, and Sacha Dietrich ask this Court to issue an administrative stay of the Food and Drug Administration's ("FDA") Emergency Use Authorization ("EUA") of the Pfizer-BioNTech COVID-19 vaccine for minor children ages five through eleven pending judicial review of Plaintiffs' complaint. Children who receive the Pfizer-BioNTech COVID-19 biologic face substantial risk of death and serious injury, while receiving little or no health benefit. The FDA's misuse of emergency powers triggers mandates by municipalities, schools, public accommodations, and medical facilities nationwide, violating the informed consent requirement of both EUA statutory authority and the Nuremberg Code, the latter of which prohibits such experimentation on un-consenting children. There are tangible injuries to Plaintiffs since FDA's actions simultaneously pose imminent injury to minors through ongoing, un-consented medical experimentation and threat of

forfeiture of fundamental freedoms. CHD is forced to divert critical resources to this issue within its mission. Plaintiffs ask this Court to urgently right this wrong.

Dated: April 15, 2022

Respectfully submitted,

/s/ Robert E. Barnes

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PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION TO STAY THE FOOD & DRUG ADMINISTRATION'S EMERGENCY USE AUTHORIZATION OF THE PFIZER-BIONTECH COVID-19 BIOLOGIC FOR CHILDREN AGES FIVE THROUGH ELEVEN

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INTRODUCTION

The FDA authorizes pharmaceutical companies to experiment on children without their consent. FDA's EUA greenlights mandates of this experimental biologic on children to the enormous profit of the pharmaceutical companies, while simultaneously immunizing these same drug companies against any liability for any injuries their products cause.

With the granting of EUA status of the Pfizer-BioNTech COVID-19 vaccine for children as young as five years old, the FDA is conducting a dangerous and unprecedented experiment. Using its emergency powers, FDA authorized an experimental biologic for children, even though no COVID-19 health emergency exists for five year old children. This drug is neither safe nor effective and does not fit the traditional definition of "vaccine," as was represented via this authorization. Despite knowledge that authorization would result in mandatory use without informed consent, Defendants engaged in neither the requisite scientific or citizen discourse, ignored citizen and scientific petitions alike, and skipped any notice-and-comment process altogether. The FDA misused its emergency powers to authorize an experimental mRNA vaccine for minor children despite serious safety concerns, inadequate testing, and outright misrepresentation of the biologic.

The FDA's action poses irreparable and immediate injury to plaintiffs and places plaintiffs' minor children at imminent risk of harm. The FDA unlawfully and injuriously mischaracterizes any purported legal source of their power, falsely represents this body-altering experimental mRNA gene therapy to be injected into children, and impermissibly redefines the word "vaccine" itself. CHD as an institution suffers and its essential resources are diverted to address this danger. The FDA claims to be above the law, the citizenry, and even this court. This suit follows, and, due to the urgent threat posed, this motion made necessary thereby.

FACTS

I. COVID-19 poses no emergency for children ages five through eleven

Defendants abused their authority under the emergency use authorization statute when it granted the EUA at issue because no "actual or potential emergency" exists for children ages five through eleven from COVID-19. 21 U.S.C. § 360bbb–3(a)(1).

Data on the risks posed from COVID-19 show that it is entirely unnecessary for children in this age group to be vaccinated. Death from COVID-19 in healthy children is statistically zero. A German study concluded that "children without comorbidities were found to be significantly less likely to suffer from a severe or fatal disease course," with the lowest risk observed in healthy children aged five through eleven.[1] Within this group, the "ICU admission rate was 0.2 per 10,000 and case fatality could not be calculated, due to an absence of cases."[2] Similarly, a Johns Hopkins study monitoring 48,000 children diagnosed with COVID "found a *mortality rate of zero* among children without a pre-existing medical condition,"[3] while a study published in Nature Medicine showed that children under 18 with no comorbidities have virtually no risk of death from COVID-19.[4] Children also have low risk of severe symptoms and hospitalization, with COVID-19 "hospitalizations occurred at a rate of 10.8 per 100,000 children," [5] and infected

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[1] Sorg, AL, Hufnagel, M., Diffloth, N. Risk of Hospitalization, severe disease, and mortality due to COVID-19 and PIMS-TS in children with SARS-CoV-2 infection in Germany, *medRxiv,* November 30, 2021, doi: https://doi.org/10.1101/2021.11.30.21267048.

[2] *Id.*

[3] Marty Makari, *The Flimsy Evidence Behind the CDC's Push to Vaccinate Children,* Wall St. J., Jul. 19, 2021, http://www.wsj.com/articles/cdc-covid-19-coronavirus-vaccine-side-effects-hospitalization-kids-11626706868.

[4] Smith, C. *et al. Deaths in children and young people in England after SARS-CoV-2 Infection during the first pandemic year,* Nat Med 28 (2022): 185-192, https://doi.org/10.1038/s41591-021-01578-1.

[5] Ward, J.L., Harwood, R., Smith, C. *et al.* Risk factors for PICU admission and death among children and young people hospitalized with COVID-19 and PIMS-TS in England during the first pandemic year. *Nat Med* 28, 193–200 (2022). https://doi.org/10.1038/s41591-021-01627-9

children often experience mild or asymptomatic disease.[6] Furthermore, epidemiological studies suggest that children do not significantly contribute to the spread of SARS-CoV-2 and that younger children may be less likely to transmit the virus.[7]

The calculated risk from COVID-19 is realistically even lower, as this "emergency" was based on inaccurate death statistics. The CDC recently corrected its COVID-19 mortality data for children, which was "inflated" in a "coding logic error" in which non-COVID-19 related deaths were counted in the statistics reduced the total pediatric deaths from COVID-19 by nearly 24% (1,755 individuals to 1,356). [8] 315 of those occurred in children ages five through eleven; this is equivalent to under 200 children per year in a population of approximately 28 million children aged five through eleven, which is ***under a 0.00000714 risk of death.*** Acknowledging this data, Florida became the first U.S. state to recommend **against** healthy children receiving this biologic, publishing guidance on March 8, 2022 that "healthy children from ages 5 to 17 may not benefit from receiving the currently available COVID-19 vaccine."[9]

II. The Pfizer-BioNTech COVID-19 "vaccine" confers no benefit to children

This biologic has proven to be monumentally less successful than the originally promised 90% effectiveness claimed by Pfizer-BioNTech. A comprehensive study of over 365,000

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[6] Encinosa, W. et al., *Severity of Hospitalizations from SARS-CoV-2 vs Influenza and Respiratory Syncytial Virus Infection in Children Aged 5 to 11 Years in 11 US States,* Feb. 21, 2022, JAMA Pediatrics, https://jamanetwork.com/journals/jamapediatrics/fullarticle/2789353.

[7] European Centrse for Disease Prevention and Control (ECDC). COVID-19 in children and the role of school settings in COVID-19 transmission. Stockholm, 2020. Available: https://www.ecdc.europa.eu/en/publications-data/children-and-school-settings-covid-19-transmission.

[8] CDC Says It Accidentally Inflated Children's COVID Death Numbers In "Coding Logic Error," *Daily Caller,* March 18, 2022, available at https://dailycaller.com/2022/03/18/cdc-data-kids-pediatric-covid-coronavirus-deaths/?s=09; COVID Data Tracker, *CDC*, updated March 21, 2022, available at https://covid.cdc.gov/covid-data-tracker/#demographics.

[9] Florida Department of Health Issues New Guidance Regarding COVID-19 Vaccination Recommendations for Children, *Florida Health,* March 8, 2022.

children ages five through eleven revealed that that biologic has an effectiveness of a *mere 12%.*[10] A study of hundreds of thousands of children in New York revealed that the COVID-19 vaccines offered "virtually no protection against infection, even within a month after full immunization."[11] What's more, a Danish study found no statistically significant positive effect against Omicron infection was seen 30 days after vaccination, and after 90 days, it conferred a *negative effectiveness*, i.e. greater susceptibility to infection.[12] This trend is seen worldwide, with highly vaccinated populations demonstrating a higher COVID-19 infection rate.

The CDC excludes COVID-19 on their published list of "vaccine-preventable diseases" for a clear reason: this COVID-19 biologic fails to prevent COVID-19. At best, it reduces the incidence of hospitalization and death, of which children are at an incredibly low risk. As COVID-19 poses an infinitesimal risk to children ages five through eleven, and none to healthy children, and vaccination is ineffective at preventing infection or transmission, there is no medical necessity, or even justification, for pediatric COVID-19 vaccination.

III. Pfizer-BioNTech's experimental "vaccine" often has severe adverse effects

While the medical benefits of pediatric COVID-19 vaccination are negligible, the known risks of a short-term adverse reaction are incredibly serious, and the full medical risks are unknown due to the speed with which this biologic was created and administered to the public.

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[10] Dorabawila, V. et al., *Effectiveness of the BNT162b2 vaccine among children 5-11 and 12-17 years in New York after the Emergency of the Omicron Variant,* Feb. 28, 2022, https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.

[11] New York Times, *Pfizer Shot Is Far Less Effective in 5- to 11-Year-Olds Than in Older Kids, New Data Show,* Feb. 28, 2022, https://www.nytimes.com/2022/02/28/health/pfizer-vaccine-kids.html.

[12] C.H. Hanson et al., *Vaccine effectiveness against SARS-CoV-2 infection with the Omicron or Delta variants following a two-dose or booster BNT162B2 or mRNA-1273 vaccination series: A Danish cohort study* (Dec. 23, 2021), https://www.medrxiv.org/content/10.1101/2021.12.20.

Evidence available prior to the EUA showed that this experimental vaccine threatens significant health risks. The Vaccine Adverse Event Reporting System (VAERS) quickly had more adverse events attributed to COVID-19 vaccines than any vaccine in history. Between November 3 and December 19, 2021, VAERS received an overwhelming 4,249 reports for children aged five through eleven years who received the Pfizer-BioNTech COVID-19 vaccine.[13] 100 of these reports were for serious events, such as fever, vomiting, increased troponin, seizure, myocarditis, and death. However, the FDA failed to adequately heed any of these warning signals prior to this authorization. Indeed, the licensure of Pfizer's COMIRNATY on August 23, 2021 required that Pfizer conduct post-marketing studies on safety, [14] demonstrating that the FDA was aware of the dangers this biologic could pose. [15] The results of these studies will not be reported to the FDA until 2023, 2024, and 2025—long after scores of children might be injured by this experimental vaccine.

Furthermore, released post-vaccination monitoring data from the FDA, who opposed the release and contended that it should occur more than 50 years from now, due to FOIA litigation demonstrate that the FDA was aware of severe health risks posed by this biologic. The FDA's report shows that within the first three months following the initial authorization of the biologic for individuals ages 16 and up, 42,086 case reports were filed containing 158,893 adverse events.[16] Of these 42,086 reports, 1,223 resulted in death. The report summarizes that:

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[13] COVID-19 Vaccine Safety in Children Aged 5-11 Years – United States, November 3-December 19, 2021, CDC, https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a1.htm#T1_down.

[14] COMIRNATY BLA Approval, *FDA,* August 23, 2021.

[15] These required studies included investigating "the occurrence of myocarditis and pericarditis," and deferred pediatric studies to evaluate the safety and effectiveness of COMIRNATY in children 12-15, children 6 months to <12 years of age, and infants <6 months of age.

[16] 5.3.6 Cumulative Analysis of Post-Authorization Adverse Event Reports of PF-07302048 (BNT162B2) Received Through 28-FEB-2021, *FDA,* April 30, 2021.

> The System Organ Classes (SOCs) that contained the greatest number (>2%) of events, in the overall dataset, were General disorders and administration site conditions (51,335 AEs), Nervous system disorders (25,957), Musculoskeletal and connective tissue disorders (17,283), Gastrointestinal disorders (14,096), Skin and subcutaneous tissue disorders (8,476), Respiratory, thoracic and mediastinal disorders (8,848), Infections and infestations (4,610), Injury, poisoning and procedural complications (5,590), and Investigations (3,693)."

An alarming number—more than 1,300—of adverse events of special interest (AESI), were also identified as potentially relevant during that time and listed in the report.[17] Many key documents containing essential clinical trial and post-vaccination data have yet to be released.

Testing specific to children yielded similar concerns. Pfizer's 12-to-15-year-old clinical trial, which included a mere 2,264 randomized adolescents, yielded side effects such as high fever, anaphylaxis, possible myocarditis and pericarditis that resulted in hospitalization, "exacerbation" of depression, neuralgia, severe abdominal pain, and lymphadenopathy.[18] There were no cases of severe COVID-19 observed in either the test or placebo group. The risk of myocarditis, a potentially fatal heart condition, for adolescents has been alarmingly high, specifically for males. The FDA itself acknowledged that the data shows "known serious risks of myocarditis" caused by this vaccine.[19] There is a higher reported rate of myocarditis in children ages 12 through 15 than in children ages 16 through 17 vaccinated against COVID-19.[20] Within 8 weeks after this biologic was offered to children 12-15 years, there were 19 times the expected

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[17] *Id.*

[18] Frenk, R., Klein, N., Kitchin, N. Safety, Immunogenicity, and Efficacy of the BNT162B2 Covid-19 Vaccine in Adolescents. N Engl J Med. 2021; 385:239-250. doi: 10.1056/NEJMoa2107456

[19] FDA, Letter to Pfizer Inc., Aug. 23, 2021, p. 6.

[20] Krug, A, Stevenson, J, Høeg, TB. BNT162b2 Vaccine-Associated Myo/Pericarditis in Adolescents: A Stratified Risk-Benefit Analysis. *Eur J Clin Invest*. 2022; 00:e13759. doi:10.1111/eci.13759

number of myocarditis cases compared to typical rates.[21] If this trend continues, then children ages five through eleven may be at an even greater risk of myocarditis than it initially appeared.

Following the clinical trials for the cohort at issue, the CDC also conducted health check-in surveys for 42,504 children for the week following vaccination. Observed adverse event occurrence and frequency published by the CDC can be observed in the following chart. [22]

TABLE 3. Reactions reported for children aged 5–11 years (N = 42,504) who completed at least one v-safe health check-in survey on days 0–7 after receiving Pfizer-BioNTech COVID-19 vaccine — United States, November 3–December 19, 2021

	% of v-safe enrollees reporting reaction or health impact*	
Event	**Dose 1 (N = 42,504)**	**Dose 2 (n = 29,899)**
Any injection site reaction	54.8	57.5
Itching	3.8	3.7
Pain	52.7	55.8
Redness	3.7	4.4
Swelling	3.9	4.9
Any systemic reaction	34.7	40.9
Abdominal pain	5.1	6.4
Myalgia	7.1	10.2
Chills	3.9	6.8
Diarrhea	2.6	2.2
Fatigue	20.1	25.9
Fever	7.9	13.4
Headache	13.9	19.8
Joint pain	2.1	2.9
Nausea	5.0	6.9
Rash	1.2	1.0
Vomiting	2.3	2.7
Any health impact	10.9	15.1
Unable to perform normal daily activities	5.1	7.4
Unable to attend school	7.9	10.9
Needed medical care	1.2	1.1
Telehealth	0.3	0.2
Clinic	0.6	0.6
Emergency visit	0.1	0.1
Hospitalization	0.02	0.02

* Percentage of enrollees who reported a reaction or health impact at least once during days 0–7 post-vaccination.

Research suggests that data on vaccine injuries are underestimates. In Germany, public health insurers report substantially larger numbers of adverse effects from COVID-19 injections that may be 8 to 10 times higher than those reported by Germany's vaccine regulatory body.[23]

The potential risks of immediate adverse effects and long-term vaccine-induced health risks outweigh any negligible benefit, and the true extent of the health risks posed by COVID-19 vaccination will not be known for years. Despite contrary evidence, the Director of the FDA's

[21] Rose, J., McCullough, P., A Report on Myocarditis Adverse Events in the U.S. Vaccine Adverse Events Reporting System (VAERS) in Association with COVID-19 Injectable Biological Products, available at https://web.archive.org/web/20211007022704/https://doi.org/10.1016/j.cpcardiol.2021.101011.
[22] *Id.*
[23] German Public Health Insurer; Vaccine Side Effects Maybe 8 to 10 Times More Frequent than Officially Reported, *eugyppius: a plague chronicle,* February 23, 2022.

Center for Biologics Evaluation and Research stated publicly that the FDA is "confident in the safety, effectiveness and manufacturing data behind this authorization" and hopes to "build confidence of parents who are deciding whether to have their children vaccinated."[24] Every child between the ages of five and eleven who sustained an injury from this vaccine has done so as a direct result of FDA's actions and false representations.

The FDA, by arbitrarily and capriciously ignoring the abundance of alarming data warning of the dangers of this biologic, has instead forged ahead on its quest of mass vaccination, no matter how heavy the costs to children and their families.

IV. Clinical trials for children ages five through eleven were insufficient

Even if the overwhelming warning signs above were absent, the clinical trial research into the Pfizer-BioNTech biologic for children five through eleven was inadequate to properly determine the safety and efficacy of the vaccine. The Phase 1 clinical trial included only 48 children.[25] To account for side effects seen with higher doses in the phase 1 clinical trial for children under 12, the FDA was forced to lower the mRNA dose to 10 μm (10 millionths of a gram) for children ages 5 through 11 in the phase 2/3 clinical trials. Yet, even at this reduced dosage, serious injury has been reported.

The Phase 2/3 clinical trial included 2,268 participants; 1,518 received the vaccine and 750 received the placebo. Side effects seen during the narrow observational period included injection-site pain, fatigue and headache, chills, muscle pain, and rashes. "Systemic events were reported more often after the second dose of BNT162b2 than after the first dose," implying that

[24] FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age, FDA, October 29, 2021.
[25] Walter, E.B., Talaat, K.R., *Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age,* The New England Journal of Medicine, Nov. 9, 2021, doi: 10.1056/NEJMoa2116298.

the more injections individuals receive, the more likely an adverse event.[26] The small trial lasted less than six months—far too short to ever know the long-term risks.

The phase 2/3 clinical trial data was published by September 6, 2021; less than two months before the EUA was granted. Normally, participants are monitored for 2 years after receiving the first dose. Defendants only had a few months of data prior to authorizing this biologic, so it was impossible to know long-term effects of the trial. The trial acknowledges that the "[l]imitations of the study include the lack of longer-term follow-up to assess the duration of immune responses, efficacy, and safety,"[27] and promises that "longer-term follow-up from this study, which will continue for 2 years, should provide clarification."[28] The study also clearly states that it was not "powered to detect potential rare side effects of BNT162b2 in 5-to-11-year-olds" and emphasizes the necessity of studies with expanded cohorts and additional safety assessments.[29] These studies were very short-term, had samples that were not representative of the total population, and had poor predictive power because of their limited size.[30] There has been virtually no investigation into these severe side effects that threaten pediatric recipients of this biologic. And yet, Defendants have nonetheless opted to authorize their use for children.

Furthermore, as FDA freely admits, the formula authorized for children five through eleven varies from the one that has been previously administered. During the Vaccine and Related Biological Products Advisory Committee (VRBPAC) meeting held to discuss the EUA at issue, the FDA stated: "the Pfizer-BioNTech COVID-19 Vaccine for use in children 5-11

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[26] *Id.*
[27] *Id.*
[28] *Id.*
[29] *Id.*
[30] Kostoff, R., Calina, D., *Why are we vaccinating children against COVID-19?,* Toxicology Report, doi: https://doi.org/10.1016/j.toxrep.2021.08.010.

years of age uses tromethamine (Tris) buffer instead of the phosphate buffered saline (PBS) as used in the previous formulation and excludes sodium chloride and potassium chloride.[31] The use of the different inactive ingredients for this cohort alone allegedly is to help stabilize the vaccine under refrigerated temperatures, but the formulation also contains medicines used for heart attacks, i.e. tromethamine and tromethamine hydrochloride, potentially to counteract the known risks of myocarditis and pericarditis in children and young adults. The biologic that is authorized for use in children five through eleven years of age includes different inactive ingredients compared to the vaccine that has been studied in clinical trials. As such, the biologic as it is being administered to young children currently is by definition untested.

V. The Pfizer-BioNTech COVID-19 biologic drug fails to meet the traditional definition of "vaccine"

The Pfizer-BioNTech COVID-19 biologic does not fall under the traditional definition of "vaccine" and has thus been continuously misrepresented by Defendants, and ultimately the pharmaceutical companies, media, and American government. Pfizer-BioNTech's experimental mRNA biologic is among the first of its kind, utilizing a brand-new delivery system and gene therapy technology. Unlike vaccines that have come before it, this biologic does not actually contain the virus, SARS-CoV-2, that causes the COVID-19 disease, but rather delivers mRNA sequences that infiltrate the body's cells and yield the production of a spike protein that mimics the SARS-CoV-2 coronavirus. The mRNA component injected into the body utilizes the host cell's own machinery to produce the spike protein. This is a different mechanism than that of

[31] Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting October 26, 2021 FDA Briefing Document EUA amendment request for Pfizer-BioNTech COVID-19 Vaccine for use in children 5 through 11 years of age.

traditional vaccines, such as inactivated, attenuated, subunit, or protein-based vaccines that do not penetrate human cells but utilize the actual virus to activate the body's immune response.

While not a "vaccine" under the traditional definition, this experimental injection does fall under the FDA Office of Cellular, Tissue, and Gene Therapies' definition of "gene therapy products," although the FDA failed to study and test it as such. Gene therapies have never been widely used in a general population and using them in this manner is still experimental.

VI. Defendants' EUA absent a stay will result in discriminatory treatment towards unvaccinated children

The history of the FDA and its role in regulating medical products has led the public to trust the FDA's actions without question. The very fact that the FDA authorized this product, instilled faith in its use and misled confidence in an experimental vaccine. Cultural and societal shifts that directly affect children have and will continue to occur as a result.

Defendants' unlawful EUA has already triggered mandates and policies that segregate and endanger vaccinated and unvaccinated children. New Orleans became the first major school district in the United States to mandate that all children ages five and up receive a COVID-19 experimental injection.[32] Furthermore, a bill proposed in California, SB 871, would require all children to receive a COVID-19 injection to attend childcare For school.[33]

Before the 5-11 EUA was even granted, there were calls from a Texas State Board of Education member to immediately add the COVID-19 vaccine to the list of public-school mandatory immunizations.[34] In his request letter to the Department of State Health Services, he

[32] Mandate to Vaccinate New Orleans Schoolchildren Kicking In, *U.S. News,* January 31, 2022.
[33] SB-871, California Legislature, 2021-2022 Legislative Session (California 2022).
[34] Texas education official calls for mandatory COVID vaccines, KHOU 11, September 4, 2021, available at https://www.khou.com/article/news/health/coronavirus/vaccine/texas-mandatory-immunizations-covid-students-school/285-bd8f997f-0cf2-49ce-a950-65014acf1e82.

argued that this step should be taken "[n]ow that the Pfizer-BioNTech vaccine has received full FDA approval."[35] The vaccine available under the 5-11 EUA is not the same as Pfizer's licensed Comirnaty, which, according to the CDC, is not yet available to the public.[36] This is an example of how school officials have been misled by FDA's bait-and-switch as well as the eagerness to mandate this biologic for young children.

Even more alarming are reports of hospitals refusing to perform organ transplants for patients who have not received a COVID-19 vaccine.[37] The Cleveland Clinic, the University of Colorado Hospital, and Brigham and Women's Hospital have all engaged in this type of abhorrent discrimination. Just recently, a North Texas teenager was denied a kidney transplant due to his vaccination status.[38] This discriminatory treatment has shockingly even applied to young children. In December 2021, a five-year-old girl in Texas who needed a kidney transplant was removed from the transplant list because she had not received the COVID-19 vaccine. Despite being medically fragile, this child and her family are being forced to choose between risking her life with an EUA experimental vaccine and being barred from receiving a life-saving transplant. This violates Defendants' assurance in its published fact sheet for this vaccine that if parents choose not to vaccinate their child, "it will not change your child's standard medical

[35] *Id.*
[36] CDC, *Covid-19 Vaccine Codes*, available at https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html.
[37] Hospitals are denying transplants for patients who aren't vaccinated against Covid, with backing from ethicists, *Stat News,* January 26, 2022, available at https://www.statnews.com/2022/01/26/hospitals-are-denying-transplants-for-patients-who-arent-vaccinated-against-covid-with-backing-from-ethicists/.
[38] Henry, S., Cook Children's Health Care System Denying Transplant to Unvaxxed Child, *Scorecard*, February 18, 2022, available at https://texasscorecard.com/state/cook-childrens-health-care-system-denying-transplant-to-unvaxxed-child/.

care."[39] This is the kind of horrific discrimination that Texas children currently face if this illicit EUA is not stayed. And such discrimination will likely only grow worse without judicial action.

Plaintiffs fear their children will experience pressure and coercion to receive the vaccine to participate in society, attend school, or have access to basic medical needs. Plaintiffs are concerned that Texas schools and municipalities may follow other states and implement discriminatory vaccine mandates as a prerequisite for school attendance or activity participation. Although Gov. Abbot has signed an executive order prohibiting COVID-19 vaccine mandates, current policies such as those at Texas hospitals exist which could certainly lead to serious physical harm or death of unvaccinated individuals, and raises concern that such an executive order is insufficient to prevent legitimate harm from befalling Plaintiffs' children.

Should this trend continue, this EUA is likely to cause mental and physical harm not only to the children who receive the biologic and suffer an adverse effect, but also to those who refrain and are subject to egregious discrimination based on the completion of an ineffectual, unnecessary, and potentially dangerous medical procedure. Legal limits on the FDA's power continue to be eviscerated using the "emergency" exceptions intended for actual emergencies, and their misappropriation and misuse by the FDA, along with the mislabeling and mis-advertising of this drug disguised as a "vaccine," pose real risks to Plaintiffs' minor children.

LEGAL STANDARD

When deciding whether to grant a stay, courts typically consider four factors: whether Plaintiffs have shown: (1) the likelihood of success on the merits, (2) the likelihood of irreparable harm to them in the absence of a stay, (3) that the balance of equities weighs in

[39] Vaccine Information Fact Sheet for Recipients and Caregivers About the Pfizer-BioNTech Covid-19 Vaccine to Prevent Coronavirus Disease 2019 (COVID-19 For Use in Individuals 5 Through 11 Years Of Age, FDA.

plaintiffs' favor, and (4) that a stay is in the public interest.[40] While authority is split regarding how to weigh certain factors or whether to use a sliding scale, in either case the "third and fourth factors, harm to the opposing party and the public interest, merge when the Government is the opposing party."[41] As the FDA and Janet Woodcock, acting in her official capacity, are an institution and employee, respectively, of the Department of Health and Human Services, the third and fourth factors merge.

The Administrative Procedures Act's (APA) stay provision allows courts to grant a stay on the proceedings in cases properly arising out of the APA. 5 U.S.C. § 705 provides that:

> When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.

The APA defines agency action as a "rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."[42]

In *Sampson v. Murray*, 415 U.S. 61 (1974), the Supreme Court relied on the APA's legislative history to observe that § 705 was intended to codify the existing power of federal courts to issue a stay.[43] While both stays and preliminary injunctions are temporary remedies, stays are different from preliminary injunctions in one important way: preliminary injunctions

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[40] *Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 25 (2008); *See also*, Fed. R. Civ. P. 65.
[41] *Nken v. Holder*, 556 U.S. 410, 420 (2009); See, e.g., *Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 51 (2008) (Ginsburg, J., dissenting); Eric J. Murdock & Andrew J. Turner, How "Extraordinary" Is Injunctive Relief in Environmental Litigation? A Practitioner's Perspective, 42 ENVTL. L. REP. NEWS & ANALYSIS 10464 (2012).
[42] 5 U.S.C. § 551(13).
[43] *Id*. at 68 n.15 (citing S. REP. NO. 752, at 230 (1945)) (citing S. REP. NO. 752, at 230 (1945)).

act on the person while stays act on the proceeding.[44]

Under APA § 705, the Court is obliged, in the interest of justice and to prevent irreparable injury, to stay the EUA that Defendants unlawfully granted to Pfizer-BioNTech's biologic for children ages five through eleven.

ARGUMENT AND AUTHORITIES

I. Petition to review EUA is likely to succeed on its merits

"The first factor, a strong showing of a likelihood of success on the merits, requires more than a mere possibility that relief will be granted."[45] In this case, there is a strong likelihood that the Court will find that FDA's EUA for Pfizer-BioNTech'sCOVID-19 vaccine for children ages five through eleven is arbitrary and capricious agency action that abuses the FDA's emergency use powers and should be invalidated.

A. The FDA's 5-11 EUA violates APA 5 U.S.C. § 706(2)(A)

The Administrative Procedures Act (APA) protects the public from arbitrary and capricious executive branch action by imposing the rule of reason and the rule of law through judicial oversight. An agency is "required to engage in reasoned decision making"[46] that requires the agency to "articulate a satisfactory explanation for its action."[47] This process requires Defendants to articulate clear rationales for decisions, especially when their actions are bound to lead to medical mandates with severe consequences for millions of people.[48] The Plaintiffs have a strong likelihood of demonstrating that Defendants have violated this requirement.

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[44] *Nken v. Holder*, 556 U.S. 418, 420 432–33. (2009).
[45] *Id*. at 420.
[46] *Michigan v. EPA*, 576 U.S. 743, 750 (2015).
[47] *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co*., 463 U.S. 29, 43 (1983).
[48] *Burlington Truck Lines v. United States*, 371 U.S. 156, 158 (1962).

Defendants abused their power in granting this EUA in three ways: (1) by disguising their authorization of this untested medical experimentation on children as "emergency" authorized power, when no such emergency authorized power so permits; (2) by misrepresenting this biologic as safe and effective "vaccine" for young children, thus denying the informed consent rights of children and their parents under both statute and the Nuremberg Code; and (3) by changing the definition of vaccine to include this biologic, reversing more than a century of medical terminology and thereby exceeding authority provided by Congress or the Constitution.

Defendants abused their emergency use power by authorizing a biologic for children where no emergency exists, there is no net benefit to children receiving the biologic, and the biologic poses significant known and unknown dangers that have yet to be properly investigated. Defendants refused to acknowledge the mild, if not nonexistent, threat that COVID-19 poses to children ages five through eleven. The EUA statute requires that to issue an authorization under § 360bbb-3, it must be reasonable to believe that "the known and potential benefits of the product . . . outweigh the known and potential risks of the product," "based on the totality of scientific evidence available."[49] However, Defendants cannot satisfy this minimum threshold in this case nor reasonably believe in this circumstance that such a determination would accurately reflect the available science and data. The FDA abused its power and shirked its obligation to, as the agency boasts, "protect[] the public health by assuring the safety, effectiveness, and security of . . . drugs, vaccines, and other biological products for human use."[50]

Defendants failed to consider relevant data regarding the adverse effects observed in the clinical trials, witnessed from the administration of this biologic, and provided to them in

[49] 21 U.S.C. § 360bbb-3(c)(2)(B).
[50] FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Children 5 through 11 Years of Age, FDA, October 29, 2021.

CHD's citizen petition. Exh. 1. Defendants authorized a biologic that has undergone insufficient clinical trials and have failed to satisfy any safety protocol regarding this biologic, ultimately encouraging a culture of false marketing and mass medical experimentation on young children. Through this EUA, the FDA has failed to provide accurate representations of the dangers and risks associated with the Pfizer-BioNTech experimental vaccine, blatantly ignoring individuals' rights of informed consent, medical freedom, and personal autonomy, as the emergency use statute so requires. As a condition of authorization under EUA, it must be ensured that "individuals to whom the product is administered are informed . . . of the significant known and potential benefits and risks of such use, and the extent to which such benefits and risks are unknown."[51] Defendants did not adequately adhere to this requirement, knowing that such an authorization would inevitably result in instances of mandatory vaccination.

Furthermore, a vaccine should confer inoculation, meaning the introduction of an infectious agent to the body to produce immunity. This biologic provides no guarantee of such a benefit. Defendants have marketed this biologic as a "vaccine" although it fails to meet the traditional definition and is in fact an experimental gene therapy.

II. Plaintiffs will suffer irreparable harm absent a stay

The FDA's EUA for the Pfizer-BioNTech vaccine will result in harm to the young children of Plaintiffs Deborah L. Else and Sacha Dietrich, the children for whom CHD advocates, and CHD as it continues to advocate against Defendants' illicit actions.

Monetary recovery is unavailable against the Defendants due to sovereign immunity, leaving declaratory and injunctive relief as the sole remedies. CHD continues to experience substantial costs incurred from the diversion of essential resources at a critical juncture due to the

[51] *Id.* at §360bbb-3(e)(1)(A)(ii).

Defendants' actions at issue here. Exh. 2. Defendants' misuse of emergency powers, misrepresentation of a dangerous biologic as a safe vaccine for children, and misappropriation power to effectively use its emergency authorization to trigger mandates of an untested product without meaningful informed consent and with no accountability due to the immunity afforded "emergency" biologics "treating" pandemics, caused and causes real economic injury to Plaintiff CHD, and this is the least dangerous injury Defendants inflict.

Plaintiffs' children are threatened by continued COVID-19 vaccine mandates and coercion from schools and pediatricians, and an inundation of pro-vaccine messaging in the media and on television, stemming directly from Defendants' inaccurate and illicit representation of safety and effectiveness, of which the Pfizer-BioNTech experimental vaccine is neither. Exh. 3 & 4. The longer this EUA remains unchecked, the more guaranteed that Plaintiffs' children, and the children on behalf of whom CHD advocates, are imminently subjected to discrimination based on their vaccination status. This EUA has already resulted in mandates of experimental mRNA gene therapy to participate in society, attend school, and even receive medical treatment. The FDA's authorization has allowed Pfizer and federal agencies to mislead the public about vaccine safety, spreading harmful misinformation to parents and children who may opt to receive it, at the behest of unconstitutional mandates, based on the FDA's authorization.

Plaintiffs' children, and indeed all Texas children, are at serious risk from these encroaching mandates. In just two short months following the 5-11 EUA, Texas hospitals began denying life-saving treatment to unvaccinated children. Any child can be involved in an accident or experience a serious illness that may put them in a situation where they require emergency treatment from a hospital or health care facility. Plaintiffs' children could die or face life-long health consequences because of the discrimination that is occurring in Texas healthcare facilities.

This deadly second-class treatment of unvaccinated children is likely to become more prevalent entirely due to Defendants' reckless action to authorize the product for this age cohort.

The FDA's nationwide authorization of Pfizer-BioNTech's experimental injection poses a severe threat to approximately 28 million young children. Aside from the known severe side effects, many of which are irreversible of the Pfizer injection, the long-term adverse effects are virtually unknown. As such, young children who are forced to receive this vaccine may become victims of the FDA's reckless actions and be subject to untold adverse effects as a direct result if this authorization. There is significant potential for harm if individuals are forced to receive a vaccine when they mistakenly believe that they are receiving a safe, effective, and licensed product for which there is some legal recourse, when in fact there is virtually no liability.

Furthermore, without a stay, Children's Health Defense will suffer harm through a substantial diversion of resources to counteract Defendants' ill-advised authorization and to correct this critical error. Exh. 2. Injury results from the marketing and expense of this action, which is imminent and ongoing, and the continued advocacy on behalf of children who have and will be injured by this EUA, without monetary remedy due to sovereign immunity.

III. A stay will not substantially injure others and furthers the public interest

Generally, when looking at the effect an action may have on the public interest, courts consider not only the law but also ethics. According to the American Medical Association, under the Code of Medical Ethics, it is a patient's right to be able to give informed consent to her physician when considering medical care or treatment.[52] Informed consent fosters trust and support in the doctor-patient relationship. It is in the public interest that those seeking vaccines

[52] *Code of Medical Ethics Opinion 2.1.1, ama-assn.org (September 5, 2021) https://www.amaassn.org/delivering-care/ethics/informed-consent*

receive accurate, truthful, complete information, and that they give informed consent or informed refusal. To be able to give informed consent, the patient must be able to understand: (1) the relevant medical information and the implications of treatment alternatives for an independent, voluntary decision; (2) the burdens, risks, and expected benefits of all options, including alternative treatments; and (3) the documentation the healthcare workers provide.

The public is served by protecting the sacred right of informed consent, especially as it pertains to EUA products. Furthermore, the American public, and especially parents and children, have an interest in ensuring that FDA is fulfilling the duty with which it was entrusted: ensuring that pharmaceutical products are reasonably safe and effective prior to release to the public. Beyond failing spectacularly in this duty with this most recent abuse of power, the FDA has taken the opposite approach: prematurely authorizing an experimental vaccine in the name of a nonexistent emergency, to the detriment of the children Defendants are tasked with protecting, and to the ultimate benefit of pharmaceutical revenue.

By granting a stay on the FDA's EUA for children ages five through eleven, this Court will end the Defendants' dangerous gamble with the lives of American children and require that they follow the law and uphold their duty to protect the American public. Parents, children, and the American people deserve no less from their government and its agents.

CONCLUSION

For the aforementioned reasons, this Court should grant Plaintiffs' Motion for Stay and direct the FDA to comply with federal law and suspend its 5-11 EUA for Pfizer-BioNTech vaccine pending judicial review of Plaintiffs' complaint.

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Respectfully submitted,

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